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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,531	07/23/2003	Jacques Colinge	64176.000005	6658

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EXAMINER

SKIBINSKY, ANNA

ART UNIT	PAPER NUMBER
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1631

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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/624,531	Applicant(s) COLINGE ET AL.	
	Examiner Anna Skibinsky	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 25-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-24 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/23/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Applicants

Amendments to claims 12-15 are acknowledged. Claims 12-24 and 59 are under examination.

Election/Restriction

Claims 1-11 and 25-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/09/2006.

Sequence Compliance

The objection regarding sequence compliance is hereby withdrawn in view of the amendments and inclusion of the sequence listing filed 3/23/07

Disclosure

The disclosure is objected to because of the following informalities: Hyperlinks are present in paragraph [0071], which should be deactivated. Appropriate correction is required.

This objection has been maintained because in the amendment filed 3/21/2007, Applicants have not deactivated the hyperlink. Applicants may overcome this objection by amending the disclosure to delete "http://" in line 4 of paragraph [0071].

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-19 and 21-24 and 59 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 12-19, 21-24 and 59 are drawn to a process for scoring a match of two peptides. The process for scoring the match involves the application of algorithms and computations of values such as the defining of an extended match E, generating a stochastic model with incorporates a probability distribution and finally scoring the extended match and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims recite a practical application; i.e. recites a useful, concrete, and tangible result. See MPEP 2106, in particular, Section IV, for an explanation of a concrete, tangible and useful result.

Claims 12-19, 21-24 and 59 do not recite a concrete, tangible AND useful result.

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2. The final outputting step does not recite a concrete, tangible AND useful result because said outputting step is tangible. However, the limitation directed to outputting encompasses the outputting of information that is related to (i.e. "based at least in part") the final scoring step but not necessarily inclusive of the scoring step. To be statutory, the claims must recite a result which is concrete, tangible AND useful. Currently, it is not clear what the result of the claimed steps is intended to be, therefore the result is not concrete. As, such, the "outputting information based at least in part on the step of scoring the extended match E" does meet the limitation of being a tangible result but does not meet the criteria of being a concrete and useful result.

3. Furthermore, paragraphs 78 and 79 of the disclosure recite that L is a ratio and comprises "E" scores. Therefore, it appears that "E" is not a calculation of whether the peptides match, it is just a theoretical score. However, L, which is calculated for E, or P seem to be the useful result which dictate the likelihood of a peptide match.

As the claims do not recite a physical transformation of matter OR a concrete, tangible and useful result, they are not directed to statutory subject matter.

Claim 20 is statutory because it recites an output of the "likelihood" which comprises a specific score and is the result of the method of claim 12, namely the determination of a match between peptides. Thus, the output of claim 20 is a result which is concrete, tangible and useful.

Response to Arguments

4. Applicant's arguments filed 3/21/07 have been fully considered but they are not persuasive.

5. Applicants argue that the amendments to claim 1, namely "outputting information based at least in part on the step of scoring the extended match E," is sufficient to produce a "tangible" result.

6. In response, the rejection is maintained because the final outputting step does not recite and concrete, tangible AND useful result. Said outputting step is tangible. However, it is not clear what the output is supposed to indicate with regard to the sequences being compared. To be statutory, the claims must recite a result which is concrete, tangible AND useful. Currently, it is not clear what the result is and thus it is not concrete.

Claim Rejections - 35 USC § 112-2nd paragraph

The rejection of claim(s) 12-24 for being Vague and Indefinite under 35 USC § 112-2nd paragraph in the Office Action filed 12/22/2006 is withdrawn in view of Applicant's Remarks/Amendments filed 3/21/2007.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-24 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 59 recite scoring the extended match E based on the likelihood ratio. It is unclear as to what is the actual value which determines the match between peptides. Paragraphs 78 and 79 of the disclosure recite that L is a ratio and comprises "E" scores. Therefore, "E" is not computed based on the likelihood ratio "L", but rather "L" is computed from the calculation of E. It appears that claim 12 is backwards. Calculation of both "P" and "L" require "E", but "E" does not require calculation of "L" or "P". Clarification is requested.

Claims 12 and 59 recite "outputting information based at least in part on the step of scoring the extended match E. This is vague and indefinite because it is not clear what information is output and it is not clear what relationship is intended between claim elements by the limitation that one element is to be "based on" another. For the purpose of examination, the information output will be construed as being the scores of the extended match.

Claims 12 and 59 recite probabilities "based on" a stochastic model. It is unclear whether or not the probabilities incorporate information from the stochastic model. It is unclear if the probabilities are the result of the model (i.e. the model actually calculates the probabilities) and if further calculations are performed using results from the model which give the probabilities.

Claims 12 and 59 recite that variables are "associated with" the candidate peptides. It is unclear as to what relationship is actually intended between "s" and the candidate peptide and whether "s" represents the sequence of the candidate peptide or if it is some fragment thereof, a homolog, an ortholog, etc.

Claims 12 and 59 recite "probabilities...are calculated" where it is unclear if this is a method step or a limitation of the probabilities. If the former, then applicant is reminded that method steps should be recited in active, not passive voice. If the latter, then it is unclear what limitation of the probabilities (variables) is intended. For the purpose of examination, this will be interpreted as a step of calculating the probabilities.

Claim 13 recites peptide match P "that characterizes" a match and fragment match F "that characterizes" a match. It is unclear if the values of P and F are numerical values of the degree of the match between the masses recited in claim 13.

Claim 13 recites limitations which are indefinite because said claim recites charge z that **is used...** and "protein/peptide modifications W **made to** the candidate peptide to match..." which seem to be recitation of either method steps OR limitations of a variable. Thus, it is unclear if these limitations are intended to be method steps or limitations of the variable.

Claims 14 and 15 recite determining an empirical probability distribution. It is unclear as to where in the method of claim 12 is this step intended to occur and what relationship is intended between this step and the other method steps recited in claim 12.

Claim 16 recites that the probabilities are based on the lemma. It is unclear as to whether the calculation is also "based on" the stochastic model recited in parent claim 12 or if it is an additional/supplemental calculation completely different from those of claim 12.

Claim 17 recites estimating the probabilities. It is unclear as to where in the method of claim 12 this step is intended to occur and what relationship is intended between this step and the other method steps recited in claim 12.

Claim 18 recites "based on" which is unclear as to whether the step of scoring the extended match in claim 18 is to replace the "scoring" of the extended match recited in claim 12. It is unclear if the extended match is somehow different from that recited in claim 12.

Claim 19 recites "based on" a learning set which is unclear as to how the learning set is intended to affect the model.

Claim 20 recites a an output generating step which is unclear as to where this limitation fits in with the method of claim 12. It is unclear as to whether the output generated in claim 20 is intended to replace the information which was output in claim 12 or if it is an additional output.

Claim 21 recites providing a theoretical fragmentation spectrum for a fragment peptide. It is unclear if this is intended to be an active method step or a limitation of the peptide. If the former, then it should be recited in an active voice. Also, it is unclear where in the method of claim 12 this step occurs and what relationship it has with the

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other steps of claim 12. If this is a limitation of the peptide, it is unclear what limitation of the peptide itself is intended by reciting a spectrum.

Claim 23 recites a step of filtering. It is unclear as to where this step occurs in the method of claim 12 and what relationship it has to the other recited steps.

Claim 23 recites "based on" making it unclear as to what is to be kept (or not) "based on" the filtering.

Claim 24 recites providing a physical sample. It is unclear as to where in the method of claim 12 this step is intended to occur and what relationship is intended between this step and the other method steps recited in claim 12.

Claim Rejections - 35 USC § 103

1. The rejection of claim(s) 12-15 and 18-24 over Bafna et al. in view of Blumenfeld et al. in the Office Action filed 12/22/06 is withdrawn in view of Applicant's Remarks/Amendments filed 3/21/2007.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Anna Skibinsky, PhD

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
5/14/07